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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,184	06/07/2001	Tadaoki Takii	010493	7678

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,184	TAKII ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12-10-04* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 10, 2004 has been entered.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Arguments

3. Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments, see remarks, filed December 10, 2004, with respect to the rejection(s)of claim(s) 1-4 under 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bienert et al. and Shalon et al.

The previous rejection claim 3 is being withdrawn for Shultz does not teach the a buffer tank with a two-port configuration as claimed by applicant. However, the specified two-port configuration is not a requirement of claim 4.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Astle et al. US 6,645,431.

Astle et al. discloses an apparatus for automated magnetic separation of materials in laboratory trays (vessel), including: a frame upon an upper surface of which a multiwell laboratory tray may be placed; a base plate on which is mounted a plurality of upstanding magnets disposed below the upper surface; and apparatus to raise the base (magnet moving means) plate such as to insert the upstanding magnets into interwell spaces in the laboratory tray.

FIG. 1 illustrates a microplate 10 having a plurality of vertical wells, as at 12, positioned over a plate of magnets 14 having a plurality of upstanding cylindrical magnets, as at 16 Wells 12 and magnets 16 are arranged such that, when microplate 10 and plate of magnets 14 are brought together, each magnet 16 will be moved into one of a plurality of positions, as at 20, in the microplate and, so disposed, each magnet will be adjacent four of the wells. Microplate 10 is shown as having 96 wells arranged in a 8.times.12 matrix and plate of magnets 14 consequently has 24 magnets. It will be

understood, however, that the invention may be applied as well to other numbers of microplate wells. In this position, the magnetic flux surrounding each magnet 16 encompasses four adjacent wells 12. Paramagnetic particles in wells 12 will be attracted by this field and will be drawn to the sidewalls of the wells, adjacent to each magnet 16. The supernate can then be withdrawn from the wells by, for example, aspiration.

Apparatus 50 includes a frame 60 having a horizontal bottom plate 62 and a horizontal top plate 64 (support plates with springs 82 located there between), the latter having a plurality of vertical holes defined therethrough, as at 66.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tyberg et al. US 6,270,726 in view of Beinert et al., US 6,506,611or in the alternative Shalon et al., US 6,309,891.

Tyberg discloses a pipetting station having a bottom sensing device is provided in conjunction with one of any known liquid level sensing devices. The bottom sensing device includes a pipetting probe **spring** mounted to a pipetting arm of the pipetting station. The bottom sensing device also includes a sensor for determining when a pipetting tip of the pipetting probe is in contact with a bottom of a tube. The bottom sensing device permits the pipetting probe to measure an exact volume of fluid in the tube by allowing the pipetting tip (suction nozzle) to be lowered to the bottom of the tube beyond the sensed fluid level.

The pipetting station 24 (moving means) includes the pipetting arm 32 (support means) that moves in the direction of arrow 42, and a pipetting probe 34 **spring** mounted to the pipetting arm 32 of the pipetting station 24. The pipetting probe 34 includes a pipetting tip 36 having a capacitive level sensor as described with reference to U.S. Pat. No. 5,648,727. The capacitive sensor senses a level of the fluid and

determines that level in relation to a known "home" position. The tube 20 is placed in a holding device (see FIG. 4) so that a bottom of the tube 20 is at the reference line "X" which is used as a reference point for discussion purposes only.

Tyberg does not disclose a guide located beneath the urging means.

Beinert et al. disclose a freely traversable metering head with numerous metering devices, wherein the metering devices are each provided individually or block-by-block with an activating device, and wherein a controller traversable with the metering head is designed for the independent operation of one or more activating devices.

The metering head with the micropipette matrix is provided with a **guide** on the mounting block, so that, when the respective actuating element is operated, the corresponding micropipette is first moved from a retracted basic position to a projecting pipetting position relative to the mounting block before the pipetting volume changes. For the first time, a metering head is provided thereby in which, as with the projecting picking needles, micropipettes are selectively moved into the pipetting position and activated individually or simultaneously in a freely addressable manner.

The invention also relates to the combination of a micropipette that exhibits a cylinder, a pipette tip and a pipette piston, which is biased relative to the cylinder by means of a pin spring, with a carrier or mount that allows the micropipette to be moved relative to the carrier parallel to the longitudinal direction of the pipette. The cylinder of the micropipette is biased relative to the carrier with a cylinder spring. The micropipette is moved relative to the carrier between two end positions via the maximal expansion or maximal compression of the cylinder spring.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Tyberg by providing a guide/mounting block as that taught by Beinert to ensure the vertical orientation of the pipette is maintained during operation.

5. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. in view of Ade et al. US 5,853,665.

Schultz et al. discloses an automated assaying system is disclosed having a multiplicity of lumens oriented and controllable in clusters. The lumens are portrayed in a matrix, wherein each row of the matrix consists of one such cluster that is individually controllable for aspiration and dispensation purposes. Also provided is a unique wash system capable of flushing the entirety of the system. A method is also depicted for accomplishing this unique assaying.

The device a hydraulic solution source 50 (buffer tank) which may contain any acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, a pump 12 (liquid conveying means) is thereafter connected thereto. Pump 12 is preferably of the peristaltic type, however, any fluid-type pump may be employed. From pump 12, a conduit 14 consisting of branch tubing coupled to, in this case, as depicted, two valves 16. The distribution valves 16 channel the wash fluid into a plurality of controllable cells 32. For example, as depicted, the distribution valves 16 provide output lines as arterial tubing 18 in equal numbers of six which spread to 12 of the housings 32 (manifold) via a valve 30 on each housing 32.

Syringes 52 (suction pump), of course, contain plungers 54 on plunger shafts 82. As there are eight syringes depicted in FIGS. 3 and 4, with four being to the front of the unit and four being to the rear, a plunger-pushing base 62 couples all of the syringe plunger shafts 82 together in any given unit. A motor 72, also coupled to a computer system, may specifically meter volumes via the syringes 52, either positively or negatively. That is, the plungers 54 may be pushed up to force fluid out of the system, or the plungers 54 may be drawn down to suction fluid into the system, both through probes 26 (suction nozzles).

As can be seen in FIGS. 4 through 6, the top spider ports 64 and the bottom spider ports 66 are slightly offset. This slight offset allows for the 180 degree rotation of an internal shaft 80 which acts as a valve key sleeve within an outer sleeve 78. That valve key sleeve 80, as depicted in FIGS. 5 and 6, contains, importantly, two grooves 74. While in an open position, those grooves orient with the spider ports 56. However, when those grooves 74 are rotated 180 degrees, they no longer align with the spider ports 56, but instead a solid portion of the key sleeve 80 orients with those ports, closing them off from the wash system downstream. Therefore, when in a closed position, the system is controllable only by syringes 52 via motors 72, but not by pump 12. Importantly, each motor 72 may be individually controlled. Therefore, as depicted in FIG. 1, each of the twelve syringe housings 32, containing eight syringes and output ports, are individually controllable via a motor 72.

Thereafter, the lumens 34 extending from tips 60 are arranged as ganged clusters within tubing management housing 20. Tubing management housing 20 is

preferably a flexible tract housing. Oriented with tubing management housing 20 is a swivel 48. Swivel 48 allows the upper portion of the tubing management housing 20 to slightly disorient or skew itself without binding of the lumens contained therein. That is, as tubing management housing 20 is moved about, swivel 48 allows that portion of tubing management housing 20 above swivel 48 to swivel freely so as not to foul. Tubing management housing 20 is also coupled to a three-dimensional robotic arm system (suction nozzle moving means), consisting of a vertical motion shaft 36, lateral motion couple 38 and longitudinal motion sleeve 40. The vertical motion shaft 36 is coupled at an upper portion to the management tubing 20, slightly below the swivel 48, and then at a lower portion to a U-shaped bracket 46 (support means).

Shultz discloses the employment of a buffer tank (50) that supplies acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, but does not disclose the buffer tank being located between the suction pump and the branch manifold.

Ade et al. discloses an apparatus for transfering fluid samples such as blood from containers. The apparatus includes an aspiration head that is connected to a vacuum pump. The system also comprises a diluent supply (buffer tank) located the pump and the point of aspiration between (implication of two ports for communication with both pump and aspiration point). After aspiration of a sample is complete, diluent solution (i.e. backwash solution) is selectively applied to the aspiration line through a solenoid-controlled valve LV2 (switching valve) located in a diluent supply line 40. The

flushing of diluent solution cleanses and prepares the aspiration line and needle for aspiration of subsequent blood samples.

As previously stated Shultz does disclose a buffer tank however, it would have been obvious to one of ordinary skill in the art to recognize that the location of the tank may be located at a point between the pump and the manifold as taught by Ade et al. to flush and wash the plumbing system between aspiration cycles.

6. Claims 1, 2, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. in view Tyberg et al. in view of Beinert et al. (as applied to claim 1 above) and further in view of Astle et al. (as applied to claim 2 above).

Schultz et al. discloses an automated assaying system is disclosed having a multiplicity of lumens oriented and controllable in clusters. The lumens are portrayed in a matrix, wherein each row of the matrix consists of one such cluster that is individually controllable for aspiration and dispensation purposes. Also provided is a unique wash system capable of flushing the entirety of the system. A method is also depicted for accomplishing this unique assaying.

The device a hydraulic solution source 50 (buffer tank) which may contain any acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, a pump 12 (liquid conveying means) is thereafter connected thereto. Pump 12 is preferably of the peristaltic type, however, any fluid-type pump may be employed. From pump 12, a conduit 14 consisting of branch tubing coupled to, in this case, as depicted, two valves 16. The distribution valves 16 channel the wash fluid into a plurality of controllable cells 32. For example, as depicted, the distribution valves 16

provide output lines as arterial tubing 18 in equal numbers of six which spread to 12 of the housings 32 (manifold) via a valve 30 on each housing 32.

Syringes 52 (suction pump), of course, contain plungers 54 on plunger shafts 82. As there are eight syringes depicted in FIGS. 3 and 4, with four being to the front of the unit and four being to the rear, a plunger-pushing base 62 couples all of the syringe plunger shafts 82 together in any given unit. A motor 72, also coupled to a computer system, may specifically meter volumes via the syringes 52, either positively or negatively. That is, the plungers 54 may be pushed up to force fluid out of the system, or the plungers 54 may be drawn down to suction fluid into the system, both through probes 26 (suction nozzles).

As can be seen in FIGS. 4 through 6, the top spider ports 64 and the bottom spider ports 66 are slightly offset. This slight offset allows for the 180 degree rotation of an internal shaft 80 which acts as a valve key sleeve within an outer sleeve 78. That valve key sleeve 80, as depicted in FIGS. 5 and 6, contains, importantly, two grooves 74. While in an open position, those grooves orient with the spider ports 56. However, when those grooves 74 are rotated 180 degrees, they no longer align with the spider ports 56, but instead a solid portion of the key sleeve 80 orients with those ports, closing them off from the wash system downstream. Therefore, when in a closed position, the system is controllable only by syringes 52 via motors 72, but not by pump 12. Importantly, each motor 72 may be individually controlled. Therefore, as depicted in FIG. 1, each of the twelve syringe housings 32, containing eight syringes and output ports, are individually controllable via a motor 72.

Thereafter, the lumens 34 extending from tips 60 are arranged as ganged clusters within tubing management housing 20. Tubing management housing 20 is preferably a flexible tract housing. Oriented with tubing management housing 20 is a swivel 48. Swivel 48 allows the upper portion of the tubing management housing 20 to slightly disorient or skew itself without binding of the lumens contained therein. That is, as tubing management housing 20 is moved about, swivel 48 allows that portion of tubing management housing 20 above swivel 48 to swivel freely so as not to foul. Tubing management housing 20 is also coupled to a three-dimensional robotic arm system (suction nozzle moving means), consisting of a vertical motion shaft 36, lateral motion couple 38 and longitudinal motion sleeve 40. The vertical motion shaft 36 is coupled at an upper portion to the management tubing 20, slightly below the swivel 48, and then at a lower portion to a U-shaped bracket 46 (support means).

Shultz discloses the employment of a buffer tank (50) that supplies acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution.

Schultz does not teach a device that comprises nozzle moving including urging means for urging the suction nozzles toward the vessel, magnet, and a magnet moving means, and a guide.

Tyberg in view of Beinert (as given above) discloses a pipetting station 24 (moving means) includes the pipetting arm 32 (support means) that moves in the direction of arrow 42, and a pipetting probe 34 **spring** (urging means) mounted to the pipetting arm 32 of the pipetting station 24. The pipetting probe 34 includes a pipetting

tip 36 having a capacitive level sensor as described with reference to U.S. Pat. No. 5,648,727. The capacitive sensor senses a level of the fluid and determines that level in relation to a known "home" position. The tube 20 is placed in a holding device (see FIG. 4) so that a bottom of the tube 20 is at the reference line "X" which is used as a reference point for discussion purposes only. As taught above it would have been obvious to modify the device of Tyberg to include a configuration of the block of Bienert which includes a guide to ensure vertical alignment of the pipette is maintained.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Schultz et al. by employing the sensing system of the modified device of Tyberg in order to prevent the probes 26 of the device of Schultz from breaking in the event that the robotic system moves the probes down to far to contact the basin 28.

As given herein above, Astle et al. discloses an apparatus for automated magnetic separation of materials in laboratory trays (vessel), including: a frame upon an upper surface of which a multiwell laboratory tray may be placed; a base plate on which is mounted a plurality of upstanding magnets disposed below the upper surface; and apparatus to raise the base (magnet moving means) plate such as to insert the upstanding magnets into interwell spaces in the laboratory tray.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the modified device of Schultz et al. by incorporating the automated magnetic system of Astle et al. to allow for automated process of separating unwanted particles from the fluid to be aspirated.

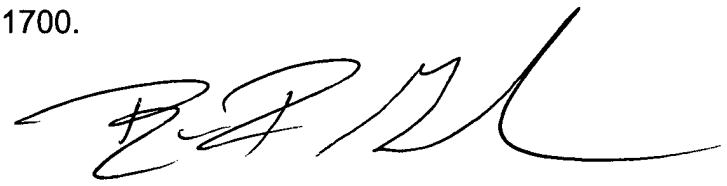
Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Isobe et al., Nakazawa et la., Ingenhoven et al., Blatter, Doktycz et al., Uffenheimer et al., and Marvin disclose dispensing/asipiration systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1700.



brg
February 11, 2005